Ameridose, LLC-Complaint file-(PHA-2010-0108) – Allegation of Complaint: manufacture and distribution of non-approved FDA products.



DEVAL L. PATRICK GOVERNOR

TIMOTHY P. MURRAY LIEUTENANT GOVERNOR

JUDYANN BIĞBY, MD . SECRETARY

JOHN AUERBACH COMMISSIONER

June 6, 2011

James N. Czaban, Esq. Wiley Rein, LLP 1776 K Street NW Washington, DC 20006

RE: Complaint Docket Nos. PHA20100107 and PHA20100108

Dear Atty. Czaban:

The Board of Registration in Pharmacy (Board) has voted to resolve the above-referenced complaints by issuing a Dismissal Letter (enclosed) to Ameridose, LLC pharmacies located in Westborough, Massachusetts.

Thank you for bringing this matter to the attention of the Board.

Very truly yours,

Stanley B. Walczyk, R.Ph, President Board of Registration in Pharmacy

Encls.

The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

Division of Health Professions Licensure

Board of Registration in Pharmacy 239 Causeway Street, Suite 500, 5th Floor Boston, MA 02114 (800) 414-0168

http://www.mass.gov/reg/boards/pharmacy



DEVAL L. PATRICK GOVERNOR

TIMOTHY P. MURRAY LIEUTENANT GOVERNOR

JUDYANN BIGBY, MD SECRETARY

JOHN AUERBACH COMMISSIONER

The Commonwealth of Massachusetts

Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure

Board of Registration in Pharmacy 239 Causeway Street, Suite 500, 5th Floor Boston, MA 02114 (800) 414-0168

http://www.mass.gov/reg/boards/pharmacy

In the Matter of:

Ameridose, LLC

205 Flanders Road

Westborough, MA 01581

Pharmacy Registration No. DS89641)

Docket No. PHA20100108

DISMISSAL LETTER

The Board of Registration in Pharmacy ("Board") investigated a complaint alleging that that on or about June 30, 2010, Ameridose, LLC, a pharmacy licensed by the Board (No. DS89641) located at 205 Flanders Road, Westborough, Massachusetts ("Pharmacy"), was engaged in the manufacture and distribution of two products that were not approved by the U.S. Food and Drug Administration; specifically, pre-mixed nicardipine injection (Nicardipine (2.5mg/ml) in 10ml glass ampoules for dilution in 240 ml of intravenous fluid) and pre-mixed Cardene ® I.V. Injection (Cardene ® I.V. 20mg or 40mg (0.1mg/ml or 0.2 mg/ml)) in 200ml Galaxy® bags.

On March 8, 2011, after review of the complaint investigative report and other information related to the complaint, including additional information provided by the complainant, the Board voted to **Dismiss the complaint without prejudice.**

The complaint and related documents are public records which will remain on file with the Board.

PER ORDER OF THE BOARD

Stanley B. Walczyk, R.Ph, President

Date: June 6, 2011

Board Dec. No.2565 cc: Complainant



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure
239 Causeway Street, Suite 200
Boston, MA 02114
Office of Public Protection
(617) 973-0865 Fax (617) 973-0985 TTY (617)-973-0895

INSPECTION REPORT

Date of Inspection 07/08/10 Reg. No. DS8964/ Expiration Date 12/3///
Purpose of Inspection New Location Relocation Compliance
Docket No. OR Staff Assignment No. PHH-Q0/0-0/07
Corporation Name AMOUNOSO
Pharmacy DBA Name + MODICOSC Store No
Address 205 Florders Road Westborough MA
Telephone No. 508-820-0606 Fax No. 508-475-042/
Manager of Record BRYON O' No. 11 Reg. No. PH 23692
Pharmacy DEA Registration No. and Expiration Date FA 122/49/ 6/3/11
Pharmacy Hours Daily 6 Saturday 6 Saturday 6 Sunday 9 Sunday
Practice Setting Community Chain With Drive-thru Window Community Independent Specialty \(\bigvec \) Long Term Care
Daily Pharmacy Volume Less than 100 100 to 500 Above 500
Staff Pharmacists (Names and Registration Numbers) See a Halheld Exp 6/30///
Pharmacy Interns (Names and Registration Numbers)
Pharmacy Technicians (Names, Registration Numbers and Certification Status)
Other Pharmacy Support Staff and Trainees (Names and positions)
lacksquare

AMERDOGE

205 Flanders Road, Westborough, MA 01581 Tel: 508-656-2633, Fax: 508-872-0044

LIST OF ALL REGISTERED PHARMACISTS

	LIST OF ALL REGI	SIERED PRIARIVIA	ACISTS
NAME	TITLE	<u>ADDRESS</u>	LICENSE#
	Staff Pharmacist		
	• •		Exp.
	Staff Pharmacist		
	Olaii i Haimatist		
and the state of t			Exp.
	Staff Pharmacist		
			Exp.
	Staff Pharmacist		
			Exp.
	Staff Phatmacist		
			Exp.
	Staff Pharmacist		
			Fro 1
			Exp. 1
	Staff Pharmacist		
•	•		Exp. 1
	Staff Phatmacist		e
			Exp.
	Staff Pharmacist		
	. Stan Fliathlacist		
			Exp. 1
	Staff Pharmacist		
		4	Exp.
	Staff Pharmacist		
	•		R
	, com		Exp.
1	Staff Pharmacist		
•			Exp.
	Staff Pharmacist		
			Exp.
	Staff Pharmacist		
	Clair I Hattilacist		
			Exp. 1
	Staff Pharmacist		
	•		Exp. 1
	Staff Pharmacist		

. <u>NAME</u>	TITLE	ADDRESS	LICENSE #
	Staff Pharmacist		Exp.
	Staff Pharmacist		
			Exp.
	Staff Pharmacist		Exp.
		- Andrews Control of the Control of	
	Staff Pharmacist		Exp.
	Staff Phatmacist		Exp.
	Staff Pharmacist		Exp.
	Mgr of Record		Exp.
	Staff Pharmacist		Exp.
	Staff Pharmacist		Ехр.
	Staff Pharmacist		Exp.
	Staff Pharmacist	F	Ехр.
	Staff Phatmacist	L 200	Ехр.
	Staff Pharmacist	8	Exp.
	•		

AMERODOSE

205 Flanders Road, Westborough, MA 01581 Tel: 508-656-2633, Fax: 508-872-0044

LIST OF ALL REGISTERED PHARMACY TECHNICIANS

LIST	OF ALL REGISTERED	PHARMACY TECHN	<u>ICIANS</u>
NAME	TITLE Registered Technician	<u>ADDRESS</u>	LICENSE #
	Registered Technician		Exp.
	Registered Technician		Exp
	Registered Technician		Exp.
	Registered Technician Registered Technician		Exp 1
	Registered Technician		Exp
	Registered Technician		Exp Exp
	Registered Technician		Exp.
	Registered Technician		Exp
	Registered Technician		Exp
	Registered Technician		

	THE TO	ADDRESS	LICENSE#
NAME	TITLE	ADDRESS	Exp 1
	Registered Technician		Exp
	Registered Technician		Exp T
	Registered Technician		Exp
	Registered Technician		Exp
	Registered Technician		Exp
	Registered Technician) Exp
	Registered Technician		Exp
	Registered Technician		Exp
	Registered Technician		Exp
	Registered Technician		Exp
	Registered Technician		Exp
	Registered Technician		Exp
	Registered Technician		Exp
	Registered Technician		Exp
	Registered Technician		Exp
•	•		

NAME	TITLE	<u>ADDRESS</u>	LICENSE #
	Registered Technician		Exp
	Registered Technician	0	
	registered remindant		Exp
	Registered Technician		
			Exp
	Registered Technician		Exp
	Registered Technician		
		V	Exp
	Registered Technician		
	Registered Technician		Exp
	registered recinical		Exp.
	Registered Technician		
			Exp.
	Registered Technician		Exp
	Registered Technician		
	• .		Exp
	Registered Technician		
	Registered Technician		Exp
	register roman		Exp
	Registered Technician		
	161		Exp
	Registered Technician		Exp
	Registered Technician		
			Exp
	Registered Technician		
	Registered Technician		Exp
	registered recumeran		Exp
	Registered Technician		
			Exp
	Registered Technician		

and the second of the second o

Exp

<u>NAME</u>	TITLE	ADDRESS	LICENSE #
	Registered Technician		Exp Exp
Thais Nunes	Registered Technician		Exp
Esther D Ocasio	Registered Technician		Exp
Francheska Ocasio	Registered Technician		Exp
Rosaleen Ocasio	Registered Technician		Exp
Merilyn Otero	Registered Technician		Exp
Aline P Parks	Registered Technician		Exp
Rosana Pessanha	Registered Technician		Exp
Tauren Petrafassi **	Registered Technician		Exp
Andrew Pfeiffer	Registered Technician		Exp
Linda Lee Phan	Registered Technician		Exp
Le L. Phyo	Registered Technician		Exp (
Mary R. Policronis	Registered Technician		Exp
Maria R. Quintanilla	Registered Technician		Exp
Metxy Ramirez	Registered Technician		Exp
Joyce V. Robles	Registered Technician		Exp
Alba Rodriguez	Registered Technician		Exp
Josephine Santos	Registered Technician		

Exp

NAME	TITLE Registered Technician	<u>ADDRESS</u>	LICENSE#
	Registered Technician		Exp
	Registered Technician		PT11874 Exp 5-9-12
	Registered Technician		1 Exp
	Registered Technician		Exp
	Registered Technician		Exp
	Registered Technician		Exp
	Registered Technician		Exp
	Registered Technician	Worcester, MA 01610	Exp 1
	Registered Technician	•	Exp
	Registered Technician	4	Exp
	Registered Technician		
	Registered Technician		Exp
	Registered Technician		Exp

JAME TITLE

ADDRESS

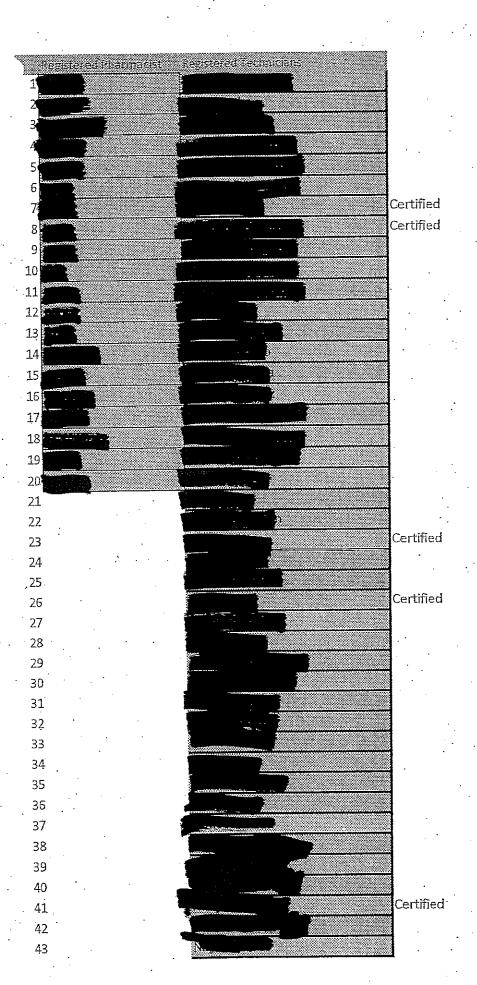
LICENSE#

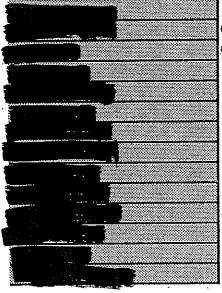
SECURITY - 247 CMR 6.02 and CFR 1301.75(b)	YES	NO.
DEQUATE SECURITY SYSTEM	i.	
VIDENCE OF SECURITY CAMERAS		
ECURITY BARRIER SEPARATES PHARMACY DEPARTMENT	1	,
ROCEDURE FOR ABSENCE OF PHARMACIST	1	-
CONTROLLED SUBSTANCES ARE LOCKED IN A SECURE CABINET OLICH (EPIGLAINE)	1	
CONTROLLED SUBSTANCES ARE DISPERSED THROUGHOUT GENERAL INVENTORY		
OSS OR THEFT OF CONTROLLED SUBSTANCES (DEA FORM 106) REPORTED TO THE BOARD		· · · · · · · · · · · · · · · · · · ·
OSS OR THEFT OF CONTROLLED SUBSTANCES (DEA FORM 100) INTERPRED PER SONNET.	- 1/	•
ECURITY/ACCESS TO PHARMACY RESTRICTED TO AUTHORIZED PERSONNEL	r -)	
COMMENTS:	• •	:
		-
		<u> </u>
LICENSURE/REGISTRATION STATUS OF PHARMACY STAFF	YES	NO
COPIES OF PHARMACIST LICENSES ARE POSTED AND CURRENT	V	
COPIES OF TECHNICIAN REGISTRATIONS ARE CURRENT AND AVAILABLE		
PROCEDURES IN PLACE TO MAINTAIN PATIENT CONFIDENTIALITY WITH REGARD TO DISCARDED PRESCRIPTION INFORMATION (e.g. SHREDDER)	V	
COMMENTS:	<u>.</u>	· ·
STANDARDS FOR PRESCRIPTION LABELING AND FORMAT	YES	ЙО
M.G.L. c. 94C, § 21 and CMR 721.000	YES	ЙО
M.G.L. c. 94C, § 21 and CMR 721.000 PHARMACIST INITIALS ON LABEL AND SERIAL NO. OF RX	YES	ио
M.G.L. c. 94C, § 21 and CMR 721.000 PHARMACIST INITIALS ON LABEL AND SERIAL NO. OF RX "BEYOND USE" DATE IS SHOWN ON LABEL	YES	ЙО
M.G.L. c. 94C, § 21 and CMR 721.000 PHARMACIST INITIALS ON LABEL AND SERIAL NO. OF RX	YES	NO
M.G.L. c. 94C, § 21 and CMR 721.000 PHARMACIST INITIALS ON LABEL AND SERIAL NO. OF RX "BEYOND USE" DATE IS SHOWN ON LABEL INVENTORY LABELED WITH BRAND, OR GENERIC NAME AND MANUFACTURER, STRENGTH, LOT NUMBER, EXPIRATION DATE. OR INTERNAL CONTROL NUMBER WHICH REFERENCES MANUFACTURER AND LOT NUMBER USED	YES	NO
M.G.L. c. 94C, § 21 and CMR 721.000 PHARMACIST INITIALS ON LABEL AND SERIAL NO. OF RX "BEYOND USE" DATE IS SHOWN ON LABEL INVENTORY LABELED WITH BRAND, OR GENERIC NAME AND MANUFACTURER, STRENGTH, LOT NUMBER, EXPIRATION DATE. OR INTERNAL CONTROL NUMBER WHICH REFERENCES MANUFACTURER AND LOT NUMBER USED LABEL COMPLIANT WITH INTERCHANGE	YES	ЙО
M.G.L. c. 94C, § 21 and CMR 721.000 PHARMACIST INITIALS ON LABEL AND SERIAL NO. OF RX "BEYOND USE" DATE IS SHOWN ON LABEL INVENTORY LABELED WITH BRAND, OR GENERIC NAME AND MANUFACTURER, STRENGTH, LOT NUMBER, EXPIRATION DATE. OR INTERNAL CONTROL NUMBER WHICH REFERENCES MANUFACTURER AND LOT NUMBER USED LABEL COMPLIANT WITH INTERCHANGE PRESCRIPTION CONTAINS ALL REQUIRED INFORMATION.	YES	МО
M.G.L. c. 94C, § 21 and CMR 721.000 PHARMACIST INITIALS ON LABEL AND SERIAL NO. OF RX "BEYOND USE" DATE IS SHOWN ON LABEL INVENTORY LABELED WITH BRAND, OR GENERIC NAME AND MANUFACTURER, STRENGTH, LOT NUMBER, EXPIRATION DATE. OR INTERNAL CONTROL NUMBER WHICH REFERENCES MANUFACTURER AND LOT NUMBER USED LABEL COMPLIANT WITH INTERCHANGE PRESCRIPTION CONTAINS ALL REQUIRED INFORMATION ORALLY COMMUNICATED PRESCRIPTIONS ARE IMMEDIATELY DOCUMENTED	YES	ЙО
M.G.L. c. 94C, § 21 and CMR 721.000 PHARMACIST INITIALS ON LABEL AND SERIAL NO. OF RX "BEYOND USE" DATE IS SHOWN ON LABEL INVENTORY LABELED WITHERAND, OR GENERIC NAME AND MANUFACTURER, STRENGTH, LOT NUMBER, EXPIRATION DATE. OR INTERNAL CONTROL NUMBER WHICH REFERENCES MANUFACTURER AND LOT NUMBER USED LABEL COMPLIANT WITH INTERCHANGE PRESCRIPTION CONTAINS ALL REQUIRED INFORMATION.	YES	ИО
M.G.L. c. 94C, § 21 and CMR 721.000 PHARMACIST INITIALS ON LABEL AND SERIAL NO. OF RX "BEYOND USE" DATE IS SHOWN ON LABEL INVENTORY LABELED WITH BRAND, OR GENERIC NAME AND MANUFACTURER, STRENGTH, LOT NUMBER, EXPIRATION DATE. OR INTERNAL CONTROL NUMBER WHICH REFERENCES MANUFACTURER AND LOT NUMBER USED LABEL COMPLIANT WITH INTERCHANGE PRESCRIPTION CONTAINS ALL REQUIRED INFORMATION ORALLY COMMUNICATED PRESCRIPTIONS ARE IMMEDIATELY DOCUMENTED	YES	ИО
M.G.L. c. 94C, § 21 and CMR 721.000 PHARMACIST INITIALS ON LABEL AND SERIAL NO. OF RX "BEYOND USE" DATE IS SHOWN ON LABEL INVENTORY LABELED WITH BRAND, OR GENERIC NAME AND MANUFACTURER, STRENGTH, LOT NUMBER, EXPIRATION DATE. OR INTERNAL CONTROL NUMBER WHICH REFERENCES MANUFACTURER AND LOT NUMBER USED LABEL COMPLIANT WITH INTERCHANGE PRESCRIPTION CONTAINS ALL REQUIRED INFORMATION ORALLY COMMUNICATED PRESCRIPTIONS ARE IMMEDIATELY DOCUMENTED	YES	ИО
M.G.L. c. 94C, § 21 and CMR 721.000 PHARMACIST INITIALS ON LABEL AND SERIAL NO. OF RX "BEYOND USE" DATE IS SHOWN ON LABEL INVENTORY LABELED WITH BRAND, OR GENERIC NAME AND MANUFACTURER, STRENGTH, LOT NUMBER, EXPIRATION DATE. OR INTERNAL CONTROL NUMBER WHICH REFERENCES MANUFACTURER AND LOT NUMBER USED LABEL COMPLIANT WITH INTERCHANGE PRESCRIPTION CONTAINS ALL REQUIRED INFORMATION ORALLY COMMUNICATED PRESCRIPTIONS ARE IMMEDIATELY DOCUMENTED COMMENTS OUTDATED ITEMS/RETURN TO STOCK	YES	ИО
M.G.L. c. 94C, § 21 and CMR 721.000 PHARMACIST INITIALS ON LABEL AND SERIAL NO. OF RX "BEYOND USE" DATE IS SHOWN ON LABEL INVENTORY LABELED WITH BRAND, OR GENERIC NAME AND MANUFACTURER, STRENGTH, LOT NUMBER, EXPIRATION DATE. OR INTERNAL CONTROL NUMBER WHICH REFERENCES. MANUFACTURER AND LOT NUMBER USED LABEL COMPLIANT WITH INTERCHANGE PRESCRIPTION CONTAINS ALL REQUIRED INFORMATION ORALLY COMMUNICATED PRESCRIPTIONS ARE IMMEDIATELY DOCUMENTED COMMENTS OUTDATED ITEMS/RETURN TO STOCK OUARANTINE AREA FOR CONTROLLED SUBSTANCE RECALLS OR EXPIRED PRODUCT		
M.G.L. c. 94C, § 21 and CMR 721.000 PHARMACIST INITIALS ON LABEL AND SERIAL NO. OF RX "BEYOND USE" DATE IS SHOWN ON LABEL INVENTORY LABELED WITH BRAND, OR GENERIC NAME AND MANUFACTURER, STRENGTH, LOT NUMBER, EXPIRATION DATE. OR INTERNAL CONTROL NUMBER WHICH REFERENCES MANUFACTURER AND LOT NUMBER USED LABEL COMPLIANT WITH INTERCHANGE PRESCRIPTION CONTAINS ALL REQUIRED INFORMATION ORALLY COMMUNICATED PRESCRIPTIONS ARE IMMEDIATELY DOCUMENTED COMMENTS OUTDATED ITEMS/RETURN TO STOCK QUARANTINE AREA FOR CONTROLLED SUBSTANCE RECALLS OR EXPIRED PRODUCT SEGREGATED FROM CURRENT INVENTORY		
M.G.L. c. 94C, § 21 and CMR 721.000 PHARMACIST INITIALS ON LABEL AND SERIAL NO. OF RX "BEYOND USE" DATE IS SHOWN ON LABEL INVENTORY LABELED WITH BRAND, OR GENERIC NAME AND MANUFACTURER, STRENGTH, LOT NUMBER, EXPIRATION DATE. OR INTERNAL CONTROL NUMBER WHICH REFERENCES MANUFACTURER AND LOT NUMBER USED LABEL COMPLIANT WITH INTERCHANGE PRESCRIPTION CONTAINS ALL REQUIRED INFORMATION ORALLY COMMUNICATED PRESCRIPTIONS ARE IMMEDIATELY DOCUMENTED COMMENTS OUTDATED ITEMS/RETURN TO STOCK OUARANTINE AREA FOR CONTROLLED SUBSTANCE RECALLS OR EXPIRED PRODUCT		
M.G.L. c. 94C, § 21 and CMR 721.000 PHARMACIST INITIALS ON LABEL AND SERIAL NO. OF RX "BEYOND USE" DATE IS SHOWN ON LABEL INVENTORY LABELED WITH BRAND, OR GENERIC NAME AND MANUFACTURER, STRENGTH, LOT NUMBER, EXPIRATION DATE. OR INTERNAL CONTROL NUMBER WHICH REFERENCES MANUFACTURER AND LOT NUMBER USED LABEL COMPLIANT WITH INTERCHANGE PRESCRIPTION CONTAINS ALL REQUIRED INFORMATION ORALLY COMMUNICATED PRESCRIPTIONS ARE IMMEDIATELY DOCUMENTED COMMENTS OUTDATED ITEMS/RETURN TO STOCK QUARANTINE AREA FOR CONTROLLED SUBSTANCE RECALLS OR EXPIRED PRODUCT SEGREGATED FROM CURRENT INVENTORY		
M.G.L. c. 94C, § 21 and CMR 721.000 PHARMACIST INITIALS ON LABEL AND SERIAL NO. OF RX "BEYOND USE" DATE IS SHOWN ON LABEL INVENTORY LABELED, WITH BRAND, OR GENERIC NAME, AND MANUFACTURER, STRENGTH, LOT NUMBER, EXPIRATION DATE. OR INTERNAL CONTROL NUMBER WHICH REFERENCES. MANUFACTURER AND LOT NUMBER USED LABEL COMPLIANT WITH INTERCHANGE PRESCRIPTION CONTAINS ALL REQUIRED INFORMATION. ORALLY COMMUNICATED PRESCRIPTIONS ARE IMMEDIATELY DOCUMENTED COMMENTS OUTDATED ITEMS/RETURN TO STOCK QUARANTINE AREA FOR CONTROLLED SUBSTANCE RECALLS OR EXPIRED PRODUCT SEGREGATED FROM CURRENT INVENTORY COMMENTS R P ROT	YES ARMON	NC
M.G.L. c. 94C, § 21 and CMR 721.000 PHARMACIST INITIALS ON LABEL AND SERIAL NO. OF RX "BEYOND USE" DATE IS SHOWN ON LABEL INVENTORY LABELED WITH BRAND, OR GENERIC NAME AND MANUFACTURER, STRENGTH, LOT NUMBER, EXPIRATION DATE. OR INTERNAL CONTROL NUMBER WHICH REFERENCES MANUFACTURER AND LOT NUMBER USED LABEL COMPLIANT WITH INTERCHANGE PRESCRIPTION CONTAINS ALL REQUIRED INFORMATION ORALLY COMMUNICATED PRESCRIPTIONS ARE IMMEDIATELY DOCUMENTED COMMENTS OUTDATED ITEMS/RETURN TO STOCK QUARANTINE AREA FOR CONTROLLED SUBSTANCE RECALLS OR EXPIRED PRODUCT SEGREGATED FROM CURRENT INVENTORY		no cevti

	Γ	· · · · · · · · · · · · · · · · · · ·
CONTROLLED SUBSTANCE RECORDS/EDT	YES	ato
21 CFR PART 1300 – 1308 and 247, CMR 5.00 (continued)		<u> </u>
TE LAST BIENNIAL INVENTORY COMPLETED AND SHOWS BEFORE OPENING OR FIFTER CLOSING MELEN GOODS, QAJAB CHARLES AND SHOWS BEFORE OPENING OR	1	
OWER OF ATTORNEY GRANTED TOPERSONS SIGNING DEA FORM 222 AND READILY AVAILABLE	V	
OWER OF ATTRONEY FORM FOR DEA FORM 222 GRANTED TO: SYCK U'NDING TESTING	1	
COMPLETE RETURN AND DESTRUCTION RECORDS OF CONTROLLED SUBSTANCES READILY	1	7
VAILABLE		<u> </u>
MERGENCY C-II PRESCRIPTION RECORDS ARE COMPLETE AND PROPERLY FILED		<u></u>
CHEDULE II PRESCRIPTION DATA TRANSMITTED BY COMPUTER ON TIME (EDT)	1.	
ENTRAL RECORD KEEPING AUTHORITY FILED WITH DEA		
DEA ORDER FORMS FILLED OUT COMPLETELY, INCLUDING DATE AND QUANTITY RECEIVED		
CII ORDER FORMS RECONCILED SATISFACTORILY		
CIII-V INVOICES RECONCILED SATISFACTORILY	1	<u> </u>
DAILY REPORTS ARE AVAILABLE, VERIFIED, AND SIGNED BY ALL PHARMACISTS INVOLVED		
CII PERPETUAL INVENTORY RECONCILED WITHIN 10 DAYS 7/6/10 PRIVA 16/28.	سنسل	<u> </u>
COMMENTS		•
	•	•
		•
	,	· · · · · · · · · · · · · · · · · · ·
TRANSFER OF PRESCRIPTIONS - 247 CMR 9.02	XES	ИО
ORRECT TRANSFER RECORDS ARE MAINTAINED AND READILY AVAILABLE	1/10	
DAILY REPORTS ARE AVAILABLE, VERIFIED AND SIGNED BY ALL PHARMACISTS INVOLVED	V/71	
PATIENT PROFILES ARE MAINTAINED		
COMMENTS		j . 1
only (VVH- of Specific)		•
	hor	n of Ho
CVVH=continuous veno-venous	-11011	notited
EQUIPMENT and REFERENCE SOURCES 247 CYIR-6.01	/ XES	NO
COMPUTER SOFTWARE NAME: EXTRO-THE COMPUTER SOFTWARE NAME:		И
TORSION BALANCE AND WEIGHTS MO HEALED DATE TO LOWO ROTATION CANONING	STON 1	
COMPOUNDING LOG MAINTAINED	V	7
APPROPRIATELY SIZED SAFETY CONTAINERS AVAILABLE AND USED ROUTINELY (16 CFR 1700) .	V	
CURRENT COPY OR E-VERSION OF APPROPRIATE COMPENDIA REFERENCE AVAILABLE	V	
CURRENT COPY OR E-VERSION OF MA BOARD OF PHARMACY REGULATIONS AVAILABLE	1/	
CURRENT COPY OR E-VERSION OF MA LIST OF INTERCHANGEABLE DRUGS AVAILABLE	V	1.
COLORDIES O IN DAILOR THOUSE		
COMMENTS Scales: Metter Tole 00 1900 POTARIS PARKWAY COLUMBUS OH 4324		
Callin Lic OH 4824	0	
1-an 1-mollon	_	•
1-000 me The		

		· · ·
CONTINUOUS QUALITY IMPROVEMENT (CQI) PROGRAM QUALITY RELATED EVENTS (QRE) - 247 CMR 15.00	YES	МО
CURRENT COPY OR E-VERSION OF CQI PROGRAM AVAILABLE	1//	
ORE DECORDS (2 YEARS) ARE MAINTAINED IN AN ORDERLY MANNER AND FILED BY DATE		
PHARMACY PROVIDES PERSONNEL WITH ONGOING CQI EDUCATION AT LEAST ANNUALLY		
POLICY AND PROCEDURES ON SITE RELATED TO THE HANDLING OF MEDICATION ERRORS		
COMMENTS		
	•	-
		· .
		1
PATIENT COUNSELING	YES	NO -
247 CMR 6.01 and 9.07; M.G.L. c. 94C, § 21A		· /:
PATIENT COUNSELING SIGNS (11" x 14") POSTED (INCLUDING DRIVE THRU)		
ADEQUATE OFFER TO COLINSEL MADE AND DOCUMENTED.		<u>/</u>
DESIGNATED CONFIDENTIAL PATIENT COUNSULTATION AREA		
COUNSELING AREA ASSURES PRIVACY AND CONFIDENTIALITY	/./	/: \· \
PROSPECTIVE DUR ON NEW PRESCRIPTIONS CONDUCTED WILL APPLICATE.	V	
COMMENTS //mited to		-
CIVITY OF CIVITY		
	:	1
SANITATION - 247 CMR 6.02 and 9.01	YES	NO.
PHARMACY (INCLUDING SINK, REFRIGERATOR, COUNTING TRAYS, AND AUTOMATED DISPENDING MACHINES) KEPT CLEAN AND ORGANIZED	V	<u></u>
REFRIGERATOR MAINTAINED WITHING RANGE COMPLIANT WITH STORAGE OF DRUGS REQUIRING REFRIDGERATION TEMP. SP COMPLIANT	i	
ROOM TEMPERATURE IS 59-77 DEGREES F.	1/	1
PRESCRIPTION COUNTER IS USED ONLY FOR PREPARING PRESCRIPTIONS		
-PRESCRIPTION DEPARTMENT HAS SPACE ADEQUATE FOR THE SIZE AND SCOPE OF PHARMACEUTICAL SERVICES PROVIDED BY THE PHARMACY	1	
SUFFICIENT EQUIPMENT TO COMPOUND AND DISPENSE PRESCRIPTIONS	IV.	1.
STNY HAS HOT AND COLD RUNNING WATER	1	
COMMENTS MUltiple all retrigs have certifications at temp logs	iel, a kmon	alibrat vetens
	,	
CENTRAL INTRAVENOUS ADMIXTURE SERVICE (CIVAS) :	YES	NO
247 CMR 6.01(5)(c)	1	
CLEAN ROOM - MINIMUM OF 72 SQUARE FEET	IV/	
CLEAN ROOM ADJACENT TO PRESCRIPTION DEPARTMENT		<u>.</u>
HOODS: HORIZONTAL-MOSTY 65/10 VERTICAL-BIOLOGICAL BLOOD PRIMITIN ROOM VERTED OUT	1	
HOODS: HORIZONTAL-MOSTY 65/70	- 1/	

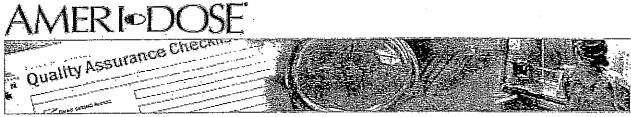
CENTRAL INTRAVENOUS ADMIXTURE SERVICE (CIVAS)	YES	ИО
CENTRAL INTRAVENOUS ADMITIZED CONTINUED 247 CMR 6.01(5)(c) continued		
747 (IVIR 0.01(5)(c) 00mma-	1://	
TITTEN QUALITY ASSURANCE GUIDELINES MAINTAINED ON PREMISES	. 1	
I KAINING IN STERILE PROCEDURE AVAILABLE AND CONDUCTED		
TOTAL TANDARDS	1.	
ADEQUATE REFERENCE STANDARDS ANNUAL CERTIFICATION OF LAMINAR HOOD AND CLEAN ROOM CONDUCTED	LK	·
COMMENTS: SCIENTIFIC OF CERTIFIES h	- HIP. Ashlar oods	νQ
	1 7790 :	NO
TECHNICIANS - 247 CMR 8.00	YES	100
CHARGE THE CLANS OPER ATE WITHIN THE SCOPE OF LAW AND ALGUMENTA	<u> </u>	
The state of the country of the coun		<u> </u>
TECHNICIANS WEAR NAME TAGS EASILY ALADAMOST TECHNICIANS FOLLOW DUTTES AS SPECIFIED IN WRITTEN POLICIES AND PROCEDURES		-
TECHNICIANS FULLOW DOTTED THE SAME AND THE S		1
TECHNICIANS ARE SUPERVISED BY A PHARMACIST		1.
COMMENTS:		
	_1	
	YES	NO
VACCINATION/CPR - 105 CMR 700.004		
PHARMACIST ADMINISTERING VACCINES TO PERSONS 18 YEARS OF AGE OR OLDER		- :-
CURRENT CPR CARD ADMINISTRATION IS CONDUCTED PURSUANT TO THE ORDER OF A PRACITIONER ADMINISTRATION IS CONDUCTED PURSUANT TO THE ORDER OF A PRACITIONER		
DOCUMENTATION OF ACCREDITED TRAINING.		_
COMMENTS:	-	
MANAGER OF RECORD (MOR) - 247 CMR 6.07	YES	NO . :
		<u> </u>
TO STATE OF A TEXA PROPERTY OF A	V	
MOR HAS COPIES OF CONFIDENTIALITY STATEMENTS TO THE MORE IS RESPONSIBLE FOR ESTABLISHING AND MONITORING POLICIES AND PROCEDURES:	: ,	
MOR IS RESPONSIBLE FOR ESTABLISHING AND MONITORING		
(a) STAFF TRAINING ONGOING	1	
(b) TECHNICIAN MANUAL ON PREMISES		
(c) RATIO PHARMACIST TO SUPPORT PERSONNEL : (X, S)		
NO ON STAFF: 6+		/
DILADMACY INTERNS		
PHARMACISTS OF PHARMACI INTEGRAL TECHS IN TRAINING REGISTERED TECHS OF TECHS IN TRAINING		
COMMENTS: Sep attached		
\sim	/	
$\mathcal{M} \cup \mathcal{M} \mathcal{M}$	<u> </u>	





Certified Certified

WHOLESALE DISTRIBUTOR INFORMATION	-	
NAME(S) OF SUPPLIERS:	taspir	Ra
Mo	Kess	\mathcal{N}
	· .	
GENERAL	YES	NO
PHARMACY GRANTED ANY WAIVERS BY THE BOARD OR DEA TO ANY LAWS OR RULES		<u> </u>
PHARMACY SHARES A REAL-TIME COMMON DATABASE WITH OTHER PHARMACIES		
PHARMACY UTILIZE THE SERVICES OF A CENTRAL FILL PHARMACY		
VERIFYING PHARMACIST(S) IS DOCUMENTED		
PHARMACY PERSONNEL WEAR APPROPRIATE NAME TAGS	نسا	
PROCEDURE TO ENSURE ALL WHO WORK IN THE PHARMACY ARE APPROPRIATELY AND CURRENTLY REGISTERED OR LICENSED AND TRAINED TO PERFORM THEIR DUTIES	V	<u></u>
SIGN(S) POSTED REGARDING PHARMACY HOURS OF OPERATION		
Fedex primarily ups some ups also courrers		
I have participated in an inspection and have reviewed the Inspection Report will Investigator: Print Name Bryan ONE Signature Title MOR License No. Investigator Manual Date OF/08/10	th the 12369	2/ -
	•	



Stability Program

Ameridose performs real-time stability indicating studies for all products. We have invested millions dollars each year to maintain the most comprehensive real-time stability indicating studies in the count following FDA Federal Code of Regulations Title 21, Sections 210 and 211 for testing. Our customers can encomplete confidence in the integrity of our products as well as documented exceptional product shelf life.

Ameridose partners with only FDA-registered third party laboratories that adhere to GLP and cGMP guidelin Our FDA-registered laboratory partners utilize HPLC and other stability indicating methodologies in the test of all of our admixtures. Ameridose has conducted independent audits of each laboratory to ensure that the standards are met and maintained.

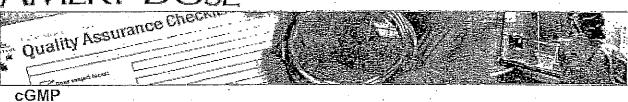
Our real-time stability studies utilize stability indicating methodology for the following criteria:

- Shifts in PH
- Homogeneity
- Particulate Matter .
- · Active Ingredient Drug Profiles
- Storage Conditions Including Temperature Cycling
- Container and Drug Interactions
- Packaging and Shipping Studies
- Light Sensitivity
- Sterile Integrity of the Container/Closure System

All contents @ copyright 2010 Ameridose, Inc. All rights reserved.

Home | Privacy Policy

AMERI-DOSE



Ameridose has moved its quality benchmark beyond USP <797> standards to meet cGMP (current Gc Manufacturing Practices), addressing requirements of the FDA for control and management of pharmaceuti production. Ameridose operates its manufacturing processes in accordance with cGMP requirements, the guaranteeing products that are consistently properly identified, correct in strength, and superior in quality we have raised the bar on quality to ensure that your patients receive the highest quality preparations.

· cGMP Requirements	Ameridose Meets cGMP
 Inbound Product Identity Verification 	 All materials used for our product are validated through a 1 verification process.
A Product Library	A sample of each lot is retained for reference.
Real-time Stability Testing	 Stability testing is done through FDA-registered third-party labora extensive criteria including potency, sterility, PH, particulate ma
Rigid Controls	 Clean rooms and hoods are monitored and routinely certified to 14644 requirements. Preparations and documentation undergo process, including multi-step quality check.
Process Validation	 Each process is tested for physical, chemical, and microbic against rigorous specifications. Media fills are completed for er on-going basis to ensure proper aseptic controls.
Product Verification	 Products are tested throughout their life-cycle to verify physic microbiological attributes.
End-product Testing	Our end-product testing program ensures the highest product qua
Continuous Audits	 Continuous testing and auditing of environment, people, and proc

AMERI-DOSE Quality Assurance Checker Quality Assurance Checker A Marian Mari

Quality Assurance & Control

Quality is the foundation of everything that we do at Ameridose. Our unsurpassed quality is driven by two I concepts, Quality Assurance and Quality Control, and, at Ameridose, these concepts are tightly linked USP<797> and cGMP requirements.

- Our strict Quality Assurance systems include novel processes and rigid controls that are set in place build quality into our preparations from the start, preventing defects before they can occur.
- Ameridose also subjects our preparations to rigorous Quality Control processes that involve testing a verification prior to release.

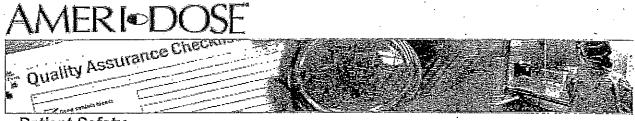
Ameridose Quality Assurance and Control Systems

SOPs and Documentation	 SOPs are in place for every process from receipt o materials through production, packaging and shipping consistency and conformity Formulary worksheets detail and document preparation product Experienced Quality Assurance professionals complet review, and store all documentation associated with end of operations
Environmental Control	 Validated, calibrated, and certified equipment Continuous monitoring of clean room environment controls, surfaces, and air quality Rigorous cleaning program utilizing rotational disinfect Clean rooms and hoods are routinely certified to 14644 compliance
Personnel Control	 Multi-level didactic training program consisting of review, task-based training, and proficiency evaluation Media fills and glove-tip monitoring to ensure prop technique
Process Validation	 Each process is tested for physical, chemical, and micr attributes against rigorous specifications Media fills are performed for each process to ensi- aseptic controls
Finished Product	 Rigorous stability program to ensure that products requirements throughout the life cycle of the products Multi-layered quality control verification process to e unit is made correctly and to the highest standards Product verification to ensure that final preparat specifications; all finished preparations are chec pharmacist
Continuous Process Improvement	Process improvements are approached from both a ti- strategic perspective

- Real time corrective and preventative actions based c root cause investigation ensure immediate remediation
 Ongoing trending for all quality systems evaluate data broader perspective to implement change from a perspective

All contents © copyright 2010 Ameridose, Inc. All rights reserved.

Home | Privacy Policy



Patient Safety

Patient safety is built into our preparation labeling and packaging. Our preparation labeling enab outstanding ease of product identification as well as compliance with Joint Commission National Patie Safety Goals 3C and 3D regarding proper medication labeling and label differentiation of look-alike, soul alike and high-alert medications.

- Over-sized font to broadcast medication name and strength
- Special safety labeling conventions that help to differentiate:
 - Look-alike, sound-alike medications
 - High and low concentrations
 - · High risk medications such as Heparin
- Bold, ISMP-recommended TALL-man lettering
- Lot number and expiration date prominently placed
- American Society of Anesthesiologists-endorsed ASTM color-coding by drug class
- OR syringes featuring medication name in horizontal and vertical formats
- NDC barcoding
- Addressing new ISMP guidelines:
 - "Unit" written out on labels to avoid confusion of the letter "u" with a zero or four
 - · Zero used before the decimal point when the dose is less than a whole unit
 - Ample space provided between drug name, dose, and unit of measure
 - Commas used to clarify dosing units of 1,000 or more

Patient safety is built into our manufacturing processes, giving you confidence that you are providing to very best preparations for your patients.

- An FDA registered manufacturer, Ameridose exceeds USP <797> standards and meets cG requirements.
- Licensed pharmacists supervise our certified and registered technicians throughout produpreparation and are responsible for verifying and releasing all final products.
- Ameridose's stability testing and special processes allow us to provide you with exceptional shelf li Our stability testing is done through FDA-registered third-party laboratories, evaluating extens criteria including potency, sterility, PH, and particulate matter.
- Process controls ensure absolute accuracy of labeled drug and strength.
- Preparations are dispensed in ready-to-use unit doses.
- Many of our products are sealed with tamper-evident caps and UV-resistant safety overwrap added protection and security.



The Commonwealth of Massachusetts

Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure
Board of Registration in Pharmacy
Investigative Report

In the Matters of:

- 1. PHA-2010-0107 Ameridose, LLC, located on 50 Fountain Street in Framingham, MA (DS3467; Issued 07/13/06)
- 2. PHA-2010-0108 Ameridose, LLC, located on 20 Flanders Road in Westborough, MA (DS89641; Issued 11/21/08)

Manger of Record:

- 1. Sophia Pasedis (PH20217; Issued 06/24/1987; no prior complaints)
- 2. Bryan M. O'Neill (PH23692; Issued 06/23/1997; no prior complaints)

Investigator: Cheryl Lathum, PharmD, RPh

Supervisor: Samuel J. Penta, RPh

Allegation of Complaint: give nature code and summarize the allegations:

The complainant (a specialty pharmaceutical company) alleges that Ameridose, LLC located on 50 Fountain Street in Framingham (DS3467; no prior complaints) and Ameridose, LLC located on 20 Flanders Road in Westborough (DS89641; no prior complaints) manufacture and distribute an unapproved, pre-mixed nicardipine injection product. The complainant further alleges that the manufacture of this product "is unavoidably dangerous under the conditions of its use and poses an immediate risk of death for critically ill patients to whom it is administered."

Nicardipine injection is a calcium channel blocker indicated for "the short-term treatment of hypertension when oral therapy is not feasible or not desirable."

There are two forms of nicardipine injection approved by the FDA. The first is nicardipine (2.5 mg/ml) in 10 ml glass ampoules, for dilution in 240 ml of intravenous fluid. It is available as Cardene IV from Inc and from various generic manufacturers. The second is Cardene I.V. Premixed Injection. It is supplied as a single-use, ready-to-use, iso-osmotic solution for intravenous administration in a 200 mL Galaxy ® container with 40 mg (0.2 mg/mL) nicardipine hydrochloride in either dextrose or sodium chloride. The pre-mixed bags are manufactured by Baxter Healthcare Corporation and marketed by

Ameridose manufacturers its pre-mixed nicardipine injection product by obtaining nicardipine ampoule products from hospital customers and by admixing the hospital's own nicardipine into commercially available diluent bags. Ameridose returns the finished products to hospitals, which store the bags until needed.

The complainant states that once diluted, nicardipine solution has a very short, 24-hour stability period at room temperature. The complainant further states, "Ameridose's practice of simply admixing nicardipine from approved ampoule products into an off-the-shelf I.V. bag cannot result in a ready-to-use nicardipine injection product that will be safe, pure, and stable beyond the 24 hour period specified in the FDA-approved labeling for ampoule products." The complainant continues, "The percent of nicardipine remaining in solution decreases as function of pH over a twenty-four hour period." The pH, concentration of the active ingredient, and the composition of the container material affect the stability of the active ingredient and the formation of impurities.

Activities and Findings:

On July 8, 2010 Board Investigators, with FDA Investigators, performed a site visit of both Ameridose's Framingham (DS3467; no prior complaints) and Westborough, Massachusetts (DS89641; no prior complaints) facilities. The MOR of the Framingham facility was identified as Sophia Pasedis (PH20217; Issued 06/24/1987; no prior complaints); the MOR of the Westborough facility was identified as Bryan M. O'Neill (PH23692; Issued 06/23/1997; no prior complaints).

At the time of the visit, the Framingham facility located on 50 Fountain Street in Framingham, MA was undergoing renovations with very limited operations and staff on site.

The Westborough facility, located on 20 Flanders Road in Westborough, was fully operational. An inspection was conducted of the facility's retail pharmacy license. No violation of Board of Pharmacy rules or regulations was found.

In a written response to allegations dated July 15, 2010, Ameridose states, "Ameridose does not manufacture this product, but rather its pharmacists are admixing the hospital's own Nicardipine into a commercially available diluent bag just as the hospital pharmacist would but rather in a far more controlled and advanced cGMP environment." Ameridose also states that "multiple stability studies, completed by independent, FDA registered labs, which show that the admixed version(s) of Nicardipine admixed by Ameridose on behalf of its client hospitals, meet all stability, pH, sterility and other final admixed product requirements."

Ameridose further states that they have "hundreds of studies that address the sterility of its admixed medications" and that all admixing occurs "in ISO 5 environments inside state of the art clean rooms." Ameridose, continues, "Ameridose's operations exceed the requirements of USP <797> and meet cGMPs."

In a written, signed letter dated January 14, 2011, and stated that and Ameridose, LLC ("Ameridose") have reached an amicable resolution to the companies' dispute regarding Ameridose's activities involving nicardipine."

The letter continues, "Accordingly, the holonger believes that any governmental investigative or enforcement actions against Ameridose are necessary to protect the public health

and safety and hereby withdraws its request that the Board of Registration in Pharmacy take any such actions."

Investigator Signature:

Date: 2/10///

Addendum:

Investigator Penta spoke with FDA Investigator on February 9, 2011. Per Investigator Emerson, at this time the FDA is not moving forward on this matter and the matter is administratively closed. If the matter is re-opened we will be contacted by FDA.



1776 K STREET NW WASHINGTON, DC 20006 PHONE 202.719.7000 FAX 202.719.7049

7925 JONES BRANCH DRIVE McLEAN, VA 22102 PHONE 703.905.2800 FAX 703.905.2820

www.wileyrein.com

Received

JAN 18 2011

BOARD OF PHARMACY

January 14, 2011

James N. Czaban 202.719.7411 jczaban@wileyrein.com

VIA UPS

James D. Coffey, Director Board of Registration in Pharmacy 239 Causeway Street, 2nd Floor, Suite 200 Boston, MA 02114 Contains Confidential Commercial Information and Trade Secrets; Exempt From Public Disclosure Pursuant to Massachusetts Public Records Law, G. L. c. 4, § 7(26)(g)

Re: Pre-Mixed Nicardipine Injection –
Notice of Settlement Between

and Ameridose LLC

Dear Mr. Coffey:

On behalf of (a), and further to our prior correspondence, I am writing to inform you that (a) and Ameridose LLC ("Ameridose") have reached an amicable resolution to the companies' dispute regarding Ameridose's activities involving nicardipine.

Accordingly, no longer believes that any governmental investigative or enforcement actions against Ameridose are necessary to protect the public health and safety and hereby withdraws its request that the Board of Registration in Pharmacy take any such actions.

We appreciate your attention to this matter.

Respectfully submitted,

ames N Czaba

.cc



June 30, 2010

VIA OVERNIGHT DELIVERY

Paul Laquerre Chief Financial Officer Ameridose, LLC 50 Fountain Street Framingham, MA 01702

Re: Manufacturing and Distribution of

Pre-Mixed Nicardipine Injection Products

Dear Mr. Laquerre:

On behalf of an unapproved injectable prescription drug product—specifically your pre-mixed nicardipine injection product. We understand that Ameridose's business model is focused on "admixing" injectable drug products into ready-to-use pre-filled i.V. bags as a convenience to hospitals and patients, and that you may see pre-filled nicardipine products as just another natural product line. However, you may not be aware of certain critical facts about nicardipine injection that we believe raise serious concerns about the safety and efficacy of your pre-mixed nicardipine product. Thus, based on the following facts, we respectfully ask that Ameridose immediately cease distributing this product in the interest of protecting the public health.

I. BACKGROUND - NICARDIPINE INJECTION PRODUCTS

It is our understanding that Ameridose manufactures a pre-mixed nicardipine injection product by obtaining nicardipine ampoule products from hospital customers, diluting and filling the modified product into off-the-shelf I.V. bags, and returning the finished product to hospitals which store the bags until needed. Because of the unique characteristics of nicardipine in the form of an injectable solution, we are concerned that your product puts patients at serious risk. For your information, these concerns are described in more detail below.

A. FDA-Approved Nicardipine Injection Products

Nicardipine injection products are indicated for "the short-term treatment of hypertension when oral therapy is not feasible or not desirable." In practice, nicardipine injections are administered to hospitalized patients with elevated blood pressure due to serious medical events such a stroke, aortic dissections, elevated blood pressure due to kidney disease, or central nervous system (CNS) injury, where rapid reduction of blood pressure as a life-saving intervention is warranted. ¹

There are two forms of nicardipine injection approved by FDA pursuant to the federal Food, Drug, and Cosmetic Act ("FDCA"):

- nicardipine (2.5 mg/mL) in 10 mL glass ampoules, for dilution in 240 mL of intravenous fluid; available from Cardene I.V. (nicardipine for injection) and from various generic manufacturers. This form of nicardipine was first approved in 1992.
- Cardene® I.V. Pre-Mixed Injection 20 mg or 40 mg (0.1mg/mL or 0.2 mg/mL), in 200 mL Galaxy® bags ("Cardene® RTU"). For each strength of Cardene® RTU there are two diluent solution options: dextrose of sodium chloride. This product form was approved in 2008.

B. Ameridose's Unapproved Nicardipine Injection Product

The Ameridose product is not FDA-approved, and as discussed below, we believe that this product is unlawful, unavoidably dangerous under the conditions of its use, and poses an immediate risk of death for critically ill patients to whom it is administered. Moreover, we believe your product is misbranded and deceptive, and that it is being unlawfully manufactured and distributed in violation of the federal Food, Drug, and Cosmetic Act ("FDCA"), as well as in violation of Massachusetts law and other state laws..

II. SAFETY RISKS

A. Nicardipine Injection Ampoules Have Very Short Stability After Being Filled Into I.V. Bags

The major drawback of nicardipine ampoules is that the product requires dilution with 240 mL of a suitable intravenous fluid before being administered by slow infusion at a final concentration of 0.1 mg./mL. Importantly, once diluted, the nicardipine solution has a very short, 24-hour stability period at room temperature. As the FDA-approved labeling for Cardene® I.V. ampoules (and equivalent generic products) warns, "THE DILUTED SOLUTION IS STABLE FOR 24 HOURS AT ROOM TEMPERATURE" (capital letters in original). Thus, for both safety and efficacy reasons, hospitals must

¹ See, Marik PE, Varon J. CHEST. 2007;131:1949-62; Qureshi AI. Circulation 2008;118:176-87; Pancioli AM. Ann. Emerg. Med. 2008;51:S24-S27.

wait until they have an identified patient in need of the drug before diluting the drug and filling it into an I.V. bag for immediate administration. Ameridose's practice of simply admixing nicardipine from approved ampoule products into an off-the-shelf I.V. bag cannot result in a ready-to-use nicardipine injection product that will be safe, pure and stable beyond the 24 hour period specified in the FDA-approved labeling for the ampoule products

B. Pre-Filled Nicardipine Injection Products Require a Highly Specialized Manufacturing Processes in Order to Overcome the Short-Stability Problem

The short-stability problem of diluted nicardipine ampoules, as well as difficulties in producing a sterile pre-filled nicardipine L.V. bag, posed technical barriers to the development of a pre-mixed ready-to-use product. However, through extensive research and development efforts was able to develop Cardene RTU as the first and only shelf-stable and sterile pre-mixed ready-to-use nicardipine injection product. FDA approved Cardene RTU in 2008. And, reflecting the novelty of, and the innovation required to develop and produce such a product, the U.S. Patent and Trademark Office (PTO) issued U.S. Patent No. 7,612,102 which covers pre-mixed ready-to-use nicardipine solution drug products. The '102 patent describes the technical difficulties that had to be addressed in order to product a safe and stable pre-mixed nicardipine product, as follows:

The production of stable, ready-to-use, premixed pharmaceutical compositions comprising nicardipine and/or its pharmaceutically acceptable salts as the active ingredient presents different development hurdles than does the development of the concentrated ampul product sold commercially as Cardene® RTM[4] I.V. As shown in FIG. 1, the percent of nicardipine remaining in solution decreases as function of pH over a twenty-four hour period. The percent decrease in nicardipine varies with the diluent and container chosen by the hospital staff.

As described in the Examples, pH, the concentration of the active ingredient, and the composition of the container material affect the stability of the active ingredient and the formation of impurities. Thus, the development of a stable, ready-to-use premixed pharmaceutical composition requires simultaneous optimization of pH and nicardipine hydrochloride concentration, as well as selection of a pharmaceutically compatible container.

² Unlike diluted solution created using nicardipine ampoules, the Cardene® I.V. Premixed solution has a stable room temperature shelf life of up to two years.

A copy of the patent can be viewed at <a href="http://patft.uspto.gov/netacgi/nph-parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=7,612,102.PN.&OS=PN/7.612,102&RS=PN/7.612,102

⁴ Here, "RTM" stands for "Ready-to-Mix."

through a combination of a modified pH range and the use of specially-designed Galaxy. I.V. bags, filled using Baxter's proprietary "Seal/Fill/Seal" aseptic manufacturing process. In the Galaxy. Seal/Fill/Seal process a special PL 2501 plastic film is sterilized by passage through a hydrogen peroxide (H₂O₂) bath in the Galaxy. machine, and the bulk solution, film, and closure components are brought together and assembled within the interior of the Seal/Fill/Seal machine. Because nicardipine is especially light-sensitive, the Galaxy. bag for the finished Cardene. RTU product uses an opaque outer film to protect the product from light-induced degradation. These processes and components for producing a shelf-stable and sterile pre-filled nicardipine product were extensively studied by and the data and results were reviewed by the FDA in connection with the approval. FDA review has been conducted with respect to Ameridose's manufacturing processes and product components.

Nicardipine ampoule products are sterile when manufactured, but that sterility is broken immediately upon opening the ampoule for dilution and filling into an I.V. bag. Where the diluted product is used immediately after being mixed, no sterility-related safety concerns would be expected. However, a pre-filled nicardipine I.V. bag that is not intended for immediate use could pose safety problems unless the entire contents and components of the product are appropriately sterilized.

is unaware of what, if any, sterilization processes Ameridose uses for its pre-filled nicardipine product, but it is important to note that terminal sterilization techniques may not be safe and effective for such products. In its development work for the Cardene RTU product, studied the use of terminal sterilization with alternative I.V. bag systems but as reported to FDA in its New Drug Application ("NDA") for Cardene RTU, "[t]erminal sterilization... impacted nicardipine hydrochloride concentration and impurity levels to an extent that development of a commercially viable terminally sterilized nicardipine hydrochloride premixed product was not feasible." The fact that Ameridose may be using sterilization techniques that have not been reviewed or approved by FDA and which may actually exacerbate the product's stability and impurity levels should be especially concerning to your company.

C. False and Misleading Stability Claims

Ameridose cannot assure the safety of its pre-filled nicardipine I.V. bags. By filling its bags at a remote location and then shipping them to its hospital customers, it is inevitable that most if not all of Ameridose's products will be used in patients far longer than 24 hours after being filled, and thus will be beyond the documented stability period for diluted nicardipine ampoules. Yet despite the serious life-threatening risk to patients posed by degraded nicardipine injection products, Ameridose's business model reflects its intent that its products be stored in hospital inventories for weeks before use. This intended use is further evidenced by the fact that, to the funderstanding, Ameridose

represents, through altered and unapproved labeling, and/or oral representations by Ameridose sales agents, that its pre-mixed nicardipine products has 75 days of shelf-life stability. This claim is directly contrary to the stability warning and instructions in the approved labeling for nicardipine ampoule products that Ameridose uses to create its pre-mixed product, and its not aware of any scientifically sound bases to support extended stability dating for Ameridose's pre-mixed product.

II. THE AMERIDOSE PRODUCT IS UNLAWFUL UNDER FEDERAL AND STATE LAWS

Ameridose's manufacturing and distribution of its pre-mixed nicardipine injection product violates the FDCA, as well as Massachusetts law and pharmacy regulations, specifically, the Code of Conduct for Registered Pharmacists, Pharmacies and Pharmacy Departments (the "Code of Conduct"), in several ways.

A. Nonconformity With Federal Law

The Ameridose product violates federal law because the product is a "new drug" and because it is not the subject of an approved New Drug Application, the product violates the FDCA. See 21 U.S.C. §§ 355(a) (requiting FDA approval of all "new drugs"), and 331(d) (prohibiting distribution of an unapproved new drug in violation of § 355). Moreover, the fact that Ameridose modifies FDA-approved nicardipine ampoules violates FDA regulations which require prior FDA approval for the types of changes Ameridose makes in converting nicardipine ampoules into pre-filled I.V. bags. See 21 C.F.R. § 314.70(b). 6

By modifying mardipine ampoules into pre-mixed I.V. bags without FDA approval, Ameridose is, directly or indirectly, circumventing the very FDA regulations that EKR followed in order to obtain approval of its NDA. Moreover, Ameridose's product is essentially an attempted (and unapproved) copy of a commercially available product—Cardene® RTU—that FDA has carefully reviewed and approved for safety and efficacy. As FDA itself has stated, this type of activity "circumvents important public health requirements and undermines the drug approval process—the evidence-based system of

⁵ See 21 U.S.C. §§ 321(p) (defining "new drug"); See also, Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609, 619, 629-30 (1973) (explaining the definition of "new drug").

⁶ Under this regulation, prior FDA approval is required for "any change in the drug substance, drug product, production process, quality controls, equipment, or facilities," including,

^{• &}quot;changes in the qualitative or quantitative formulation of the drug product, including inactive ingredients...."

 [&]quot;changes that may affect drug substance or drug product sterility assurance..."

[&]quot;changes in a drug product container closure system that controls the drug product delivered to the patient or changes in the type... (e.g., glass to high density polyethylene (HDPE), HDPE to polyvinyl chloride, vial to syringe)...of a packaging component that may affect the impurity profile of the drug product...."

drug review that consumers and health professionals rely on for safe and effective drugs."

In addition, The Ameridose pre-filled nicardipine I.V. product is misbranded in violation of the FDCA because, to inderstanding, Ameridose distributes its product in brown paper wrappers, and represents, through new labeling or otherwise, that the product is stable for 75 days from the date of its manufacture. A drug product is misbranded under the Act "[i]f its labeling is false or misleading in any particular," or if "it is dangerous to health when used in the dosage or manner... suggested in the labeling thereof." 21 U.S.C. §§ 352(a), 352(j). In addition, the Ameridose product may be misbranded under 21 U.S.C. § 352(f) if it is distributed without the FDA-approved labeling for the nicardipine ampoule product that the company uses as its source for the nicardipine in the pre-mixed product.

Ameridose cannot properly claim that its product is a "pharmacy compounded" product exempt from FDA regulation. FDA has long been concerned about companies which claim to be "compounding pharmacies," but in fact are manufacturing unapproved new drugs in violation of the FDCA. As described in the agency's Compliance Policy Guidance on Pharmacy Compounding (the "Compounding CPG"):

Some "pharmacies" that have sought to find shelter under and expand the scope of the exemptions applicable to traditional retail pharmacies have claimed that their manufacturing and distribution practices are only the regular course of the practice of pharmacy. Yet, the practices of many of these entities seem far more consistent with those of drug manufacturers and wholesalers than with those of retail pharmacies.

[W]hen the scope and nature of a pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new drug, adulteration, or misbranding provisions of the Act, FDA has determined that it should seriously consider enforcement action.⁸

B. Violation of Massachusetts Pharmacy Law

Ameridose holds six (6) Massachusetts Pharmacy, licenses between its two Massachusetts locations:

Framingham, MA

Westborough, MA

⁷ Statement of Steven K. Galson, CDER, "Federal and State Role in Pharmacy Compounding and. Reconstitution: Exploring the Right Mix to Protect Patients," before the S. Comm. on Health, Ed., Labor, and Pensions (Oct. 23, 2003) (emphasis added).

⁸ FDA Compliance Policy Guide Manual, § 460 200 (2002).

DS3467 (Retail Drug Store) CS3467 (Controlled Substance) CF3467 (Cert. of Fitness) DS89641 (Retail Drug Store) CS89641 (Controlled Substance) CF89641 (Cert. of Fitness)

Accordingly, Ameridose is required to comply with the Massachusetts Pharmacy Code of Conduct as codified at 247 Code of Massachusetts Regulations ("CMR"). Based on the foregoing, we believe that by manufacturing and distributing its pre-filled nicardipine injection product, the company is violating at least the following provisions of the Code of Conduct:

- 247 CMR § 9.01(1) (Non-conformity with federal law);
- 247 CMR § 9.01(2) (Activities intended to circumvent the law);
- 247 CMR § 9.01(6) (Deceptive Acts);
- 247 CMR § 9.01(10) (Distributing Expired, Outdated and Substandard Drugs)

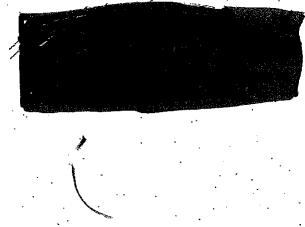
Please be advised that we have notified both the FDA and the Massachusetts Board of Registration in Pharmacy about our concerns concerning your pre-mixed nicardipine product.

CONCLUSION

We sincerely hope that in light of this information you will take the appropriate and responsible action to protect the lives and well-being of patients, by immediately discontinuing any further manufacturing and distribution of your pre-filled nicardipine injection products. If you fail to take such action will take such additional action as it deems necessary and appropriate.

Please contact the undersigned within seven (7) days with details of your intended plan of action in this matter. Thank you for your anticipated courtesy and cooperation.

Respectfully submitted,





1776 K STREIT NW WASHINGTON, DC 20006 PHDNE 202719,7000 FAX 202,719,7049

7925 JONES BRANCH DRIVE McLEAN, VA 22102 PHONE 703.905.2800 FAX 703.905.2820

www.wileyrein.com

June 30, 2010

James N. Czaban 202.719.7411 jczaban@wileyrein.com

VIA E-MAIL AND OVERNIGHT DELIVERY

James D. Coffey, Director Board of Registration in Pharmacy 239 Causeway Street, 2nd Floor, Suite 200 Boston, MA 02114

Re: Complaint Against Ameridose LLC for Unlawful

Manufacturing and Distribution of
Pre-Mixed Nicardipine Injection Products

Dear Mr. Coffey:

On behalf of I am writing to call your attention to serious violations of Massachusetts pharmacy laws and regulations by Ameridose, LLC ("Ameridose"), of Framingham and Westborough, Massachusetts, and to request that prompt investigation and disciplinary actions be taken against Ameridose by the Board of Registration in Pharmacy (the "Board").

The unlawful actions of Ameridose involve the manufacturing and distribution of an unapproved injectable prescription drug product – specifically a pre-mixed nicardipine injection product – which is unavoidably dangerous under the conditions of its use and poses an immediate risk of death for critically ill patients to whom it is administered.

As indicated below, Ameridose is a Massachusetts-based company with two Massachusetts facilities, and holds six Massachusetts Pharmacy Licenses:

Ameridose, LLC 50 Fountain Street Framingham, MA 01702 Phone: 888-820-0622 Phone: 508-656-2649 Fax: 508-872-0044

Mass. Pharmacy Licenses: DS3467 (Retail Drug Store) CS3467 (Controlled Substance) CF3467 (Cert. of Fitness) Ameridose, LLC 205 Flanders Road Westborough, MA 01581 Phone: 888-820-0622 Phone: 508-656-2649 Fax: 508-872-0044

Mass. Pharmacy Licenses; DS89641 (Retail Drug Store) CS89641 (Controlled Substance) CF89641 (Cert. of Fitness)



Thus the Board has jurisdiction, and the legal obligation, to investigate this matter and take appropriate disciplinary action to enforce the law and protect the public health.

I. BACKGROUND - NICARDIPINE INJECTION PRODUCTS

A. FDA-Approved Products

Nicardipine injection products are indicated for "the short-term treatment of hypertension when oral therapy is not feasible or not desirable." In practice, nicardipine injections are administered to hospitalized patients with elevated blood pressure due to serious medical events such a stroke, aortic dissections, elevated blood pressure due to kidney disease, or central nervous system (CNS) injury, where rapid reduction of blood pressure as a life-saving intervention is warranted.¹

There are two forms of nicardipine injection approved by FDA pursuant to the federal Food, Drug, and Cosmetic Act ("FDCA"):

- Nicardipine (2.5 mg/mL) in 10 mL glass ampoules, for dilution in 240 mL of infravenous fluid; available from EKR as Cardene IV. (nicardipine for injection) and from various generic manufacturers. This form of nicardipine was first approved in 1992.
- Cardene® I.V. Pre-Mixed Injection 20 mg or 40 mg (0.1mg/inL or 0.2 mg/mL), in 200 mL Galaxy® bags ("Cardene® RTU"). For each strength of Cardene® RTU there are two diluent solution options: dextrose or sodium chloride. This product form was approved in 2008.

B. Ameridose's Unapproved Nicardipine Injection Product

Ameridose manufactures its pre-mixed nicardipine injection product by obtaining nicardipine ampoule products from hospital customers, diluting and filling the modified product into off-the-shelf I.V. bags, and returning the finished product to hospitals which store the bags until needed. The Ameridose product is not FDA-

See P.E. Marik & J. Varon, 131 CHEST 1949-62 (2007); A.I. Qureshi, 118 Circulation 176-87 (2008); A.M. Pancioli, 51 Ann. Emerg. Med. S24-S27 (2008).



approved, and as discussed below, it is unavoidably dangerous under the conditions of its use, poses an immediate risk of death for patients to whom it is administered, is misbranded and deceptive, and is being unlawfully manufactured and distributed in violation of the FDCA and Massachusetts law.

II. AMERIDOSE'S PRE-FILLED NICARDIPINE INJECTION PRODUCT POSES SERIOUS SAFETY RISKS

A. Nicardipine Injection Ampoules Have Very Short Stability After Being Filled Into I.V. Bags

The major drawback of nicardipine ampoules is that the product requires dilution with 240 mL of a suitable intravenous fluid before being administered by slow infusion at a final concentration of 0.1 mg/mL. Importantly, once diluted, the micardipine solution has a very short, 24-hour stability period at room temperature. As the FDA-approved labeling for Cardene LV. ampoules (and equivalent generic products) warns, "THE DILUTED SOLUTION IS STABLE FOR 24 HOURS AT ROOM TEMPERATURE" (capital letters in original). Thus, for both safety and efficacy reasons, hospitals must wait until they have an identified patient in need of the drug before diluting the drug and filling it into an LV. bag for immediate administration. Ameridose's practice of simply admixing nicardipine from approved ampoule products into an off-the-shelf LV. bag cannot result in a ready-to-use nicardipine injection product that will be safe, pure and stable beyond the 24 hour period specified in the FDA-approved labeling for the ampoule products.

B. Ameridose's Manufacturing Process Cannot Overcome the Short-Stability Problem

The short-stability problem of diluted nicardipine ampoules, as well as difficulties in producing a sterile pre-filled nicardipine LV. bag, posed technical barriers to the development of a pre-mixed ready-to-use product. However, through extensive research and development efforts, was able to develop Cardene RTU as the first and only shelf-stable and sterile pre-mixed ready-to-use nicardipine injection product. FDA approved Cardene RTU in 2008. And, reflecting the novelty of Cardene RTU, and the innovation required to develop and produce such a product,

² Unlike diluted solution created using nicardipine ampoules, the Cardene® I.V. Premixed solution has a stable room temperature shelf life of up to two years.



かける・ 知[一年の後代

Massachusetts Board of Registration in Pharmacy June 30, 2010 Page 4

the U.S. Patent and Trademark Office ("PTO") issued U.S. Patent No. 7,612,102 (the '102 Patent) which covers pre-mixed ready-to-use nicardipine solution drug products. The '102 patent describes the technical difficulties that must be addressed in order to product a safe and stable pre-mixed nicardipine product as follows:

مني مانون شاخ والمناز

The production of stable, ready-to-use, premixed pharmaceutical compositions comprising nicardipine and/or its pharmaceutically acceptable salts as the active ingredient presents different development hurdles than does the development of the concentrated ampul product sold commercially as Cardene® RTM[4] LV. As shown in FIG. 1, the percent of nicardipine remaining in solution decreases as function of pH over a twenty-four hour period. The percent decrease in nicardipine varies with the diluent and container chosen by the hospital staff.

As described in the Examples, pH, the concentration of the active ingredient, and the composition of the container material affect the stability of the active ingredient and the formation of impurities. Thus, the development of a stable, ready-to-use premixed pharmaceutical composition requires simultaneous optimization of pH and nicardipine hydrochloride concentration, as well as selection of a pharmaceutically compatible container.

'102 Patent, § 5.2 (emphasis added).

solved the stability and sterility problems for pre-mixed nicardipine products through a combination of a modified pH range and the use of specially-designed Galaxy[®] I.V. bags, filled using Baxter's proprietary "Seal/Fill/Seal" aseptic manufacturing process. In the Galaxy[®] Seal/Fill/Seal process a special PL 2501 plastic film is sterilized by passage through a hydrogen peroxide (H₂O₂) bath in the Galaxy[®] machine, and the bulk solution, film, and closure components are brought together and assembled within the interior of the Seal/Fill/Seal machine. Because

³ A copy of the patent can be viewed at <a href="http://patft.uspto.gov/netacgi/mph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchmum.htm&r=1&f=G&]=50&s1=7.612.102.PN.&OS=PN/7.612.102&RS=PN/7.612.102.

⁴ Here, "RTM" stands for "Ready-to-Mix."



nicardipine is especially light-sensitive, the Galaxy® bag for the finished Cardene® RTU product uses an opaque outer film to protect the product from light-induced degradation. These processes and components for producing a shelf-stable and sterile pre-filled nicardipine product were extensively studied by and the data and results were reviewed by the FDA in connection with the approval of NDA for the Cardene® RTU product. See NDA 19-734/S-013 and S-014. No such FDA review has been conducted with respect to Ameridose's manufacturing processes and product components.⁵

Nicardipine ampoule products are sterile when manufactured, but that sterility is broken immediately upon opening the ampoule for dilution and filling into an I.V. bag. Where the diluted product is used immediately after being mixed, no sterility-related safety concerns would be expected. However, a pre-filled nicardipine I.V. bag that is not intended for immediate use could pose safety problems unless the entire contents and components of the product are appropriately sterilized.

filled nicardipine product, but it is important to note that terminal sterilization techniques may not be safe and effective for such products. In its development work for the Cardene® RTU product, studied the use of terminal sterilization with alternative I.V. bag systems but as reported to FDA in its New Drug Application ("NDA") for Cardene® RTU, "[t]erminal sterilization... impacted nicardipine hydrochloride concentration and impurity levels to an extent that development of a commercially viable terminally sterilized nicardipine hydrochloride premixed product was not feasible." NDA No. 19-734/S-013, Module 2, Table P.2.2-2. The fact that Ameridose may be using sterilization techniques that have not been reviewed or approved by FDA and which may actually exacerbate the product's stability and impurity levels should be especially concerning to the Board.

C. Ameridose's False and Misleading Stability Claims

Ameridose cannot assure the safety of its pre-filled nicardipine LV. bags. By filling its bags at a remote location and then shipping them to its hospital customers, it is

⁵ It is notable that Ameridose has had manufacturing problems in the recent past, specifically, a 2008, recall of pre-fliled fentanyl LV. bags due to super-potency. See FDA Enforcement Report at www.fda.gov/Safety/Recalls/EnforcementReports/2008/ucm120532.htm.



inevitable that most if not all of Ameridose's products will be used in patients far longer than 24 hours after being filled, and thus will be beyond the documented stability period for diluted nicardipine ampoules. Yet despite the serious life-threatening risk to patients posed by degraded nicardipine injection products, Ameridose's business model reflects its intent that its products be stored in hospital inventories for weeks before use. This intended use is further evidenced by the fact that, the inderstanding, Ameridose represents, through altered and unapproved labeling, and/or oral representations by Ameridose sales agents, that its pre-mixed nicardipine products has 75 days of shelf-life stability. This claim is directly contrary to the stability warning and instructions in the approved labeling for nicardipine ampoule products that Ameridose uses to create its pre-mixed product, and EKR is not aware of any scientifically sound bases to support extended stability dating for Ameridose's pre-mixed product.

II. THE AMERIDOSE PRODUCT IS UNLAWFUL UNDER MASSACHUSETTS LAW

Ameridose's manufacturing and distribution of its pre-mixed nicardipine injection product violates Massachusetts law and the Board's regulations, specifically, the Code of Conduct for Registered Pharmacists, Pharmacies and Pharmacy Departments (the "Code of Conduct"), 247 Code of Massachusetts Regulations § 9.01, law in several ways.

A. Nonconformity With Federal Law in Violation of § 9.01(1).

The Code of Conduct, § 9.01(1), requires that "a registered pharmacist shall at all times conduct professional activities in conformity with federal, state and municipal laws, ordinances and/or regulations, including the regulations of the Board." Ameridose is in violation of § 9.01(1) because its pre-mixed nicardipine injection product violates federal law. Specifically, the Ameridose product is a "new drug" and because it is not the subject of an approved New Drug Application, the product violates the FDCA. See 21 U.S.C. §§ 355(a) (requiring FDA approval of all "new drugs"), 331(d) (prohibiting distribution of an unapproved new drug in violation of § 355). Moreover, the fact that Ameridose modifies FDA-approved nicardipine ampoules violates FDA regulations which require prior FDA approval for the types

See 21 U.S.C. §§ 321(p) (defining "new drug"); see also Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609, 619, 629-30 (1973) (explaining the definition of "new drug").



of changes Ameridose makes in converting nicardipine ampoules into pre-filled LV. bags. See 21 C.F.R. § 314.70(b).

B. Dispensing a Drug in a Manner Intended To Circumvent Law in Violation of § 9.01(2).

The Code of Conduct, § 9.01(2), also prohibits a pharmacist from dispensing a drug "in a manner which is intended, either directly or indirectly, to circumvent the law." By modifying nicardipine ampoules into pre-mixed LV. bags without FDA approval, Ameridose is, directly or indirectly, circumventing the very FDA regulations that EKR followed in order to obtain approval of its NDA, and thus violates § 9.01(2).

Moreover, Ameridose's product is essentially an attempted (and unapproved) copy of a commercially available product — Cardene® RTU — that FDA has carefully reviewed and approved for safety and efficacy. As FDA itself has stated, this type of activity "circumvents important public health requirements and undermines the drug approval process — the evidence-based system of drug review that consumers and health professionals rely on for safe and effective drugs."

In addition, any representation by Ameridose that its product is a "pharmacy compounded" product exempt from FDA regulation would be false and would also reflect an intent to circumvent the requirements of federal law. FDA has long recognized the deceptive and evasive intent of some companies claiming to be

⁷ Under this regulation, prior FDA approval is required for "any change in the drug substance, drug product, production process, quality controls, equipment, or facilities," including,

 [&]quot;changes in the qualitative or quantitative formulation of the drug product, including inactive ingredients..."

^{· &}quot;changes that may affect drug substance or drug product sterility assurance..."

[&]quot;changes in a drug product container closure system that controls the drug product delivered to the patient or changes in the type...(e.g., glass to high density polyethylene (HDPE), HDPE to polyvinyl chloride, vial to syringe)... of a packaging component that may affect the impurity profile of the drug product..."

Statement of Steven K. Galson, CDER, "Federal and State Role in Pharmacy Compounding and Reconstitution: Exploring the Right Mix to Protect Patients," before the S. Comm. on Health, Ed., Labor, and Pensions (Oct. 23, 2003) (emphasis added).



"compounding pharmacies," as described in the agency's Compliance Policy Guidance on Pharmacy Compounding (the "Compounding CPG"):

Some "pharmacies" that have sought to find shelter under and expand the scope of the exemptions applicable to traditional retail pharmacies have claimed that their manufacturing and distribution practices are only the regular course of the practice of pharmacy. Yet, the practices of many of these entities seem far more consistent with those of drug manufacturers and wholesalers than with those of retail pharmacies.

[W]hen the scope and nature of a pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new drug, adulteration, or misbranding provisions of the Act, FDA has determined that it should seriously consider enforcement action.

C. Deceptive Acts in Violation of § 9.01(6)

The Code of Conduct, § 9.01(6), requires that "[a] pharmacist shall not engage in any fraudulent or deceptive act." Ameridose is committing deceptive acts in violation of § 9.01(6) because, to inderstanding, Ameridose represents, through new labeling, sales representative statements, or otherwise, that the product is stable for 75 days from the date of its manufacture when in fact, according to FDA, a diluted nicardipine ampoule product is not stable beyond 24 hours. Ameridose's representations regarding extended stability of its product are therefore deceptive in violation of Code of Conduct § 9.01(1), and also render the product misbranded in violation of the FDCA, which provides that a drug product is misbranded "[i]f its labeling is false or misleading in any particular," or if "it is dangerous to health when used in the dosage or manner...suggested in the labeling thereof." 21 U.S.C. §§ 352(a), 352(j).

PDA Compliance Policy Guide Manual, § 460.200 (2002).



D. Distributing Expired, Ontdated and Substandard Drugs in Violation of § 9.01(10)

The Code of Conduct, § 9.01(10), also generally prohibits pharmacists from "dispens[ing] or distribut[ing] expired, outdated or otherwise substandard drugs..." As described above, Ameridose's pre-mixed nicardipine injection product expires and becomes outdated a mere 24 hours after it is mixed, yet as distributed by Ameridose and used by hospitals, the product is not used in patients until days or weeks after it has expired. Thus, Ameridose is also violating Code of Conduct section 9.01(1) by its manufacturing and distribution of its pre-mixed nicardipine injection product.

III. THE BOARD CAN AND SHOULD TAKE PROMPT DISCIPLINARY ACTION AGAINST AMERIDOSE

Under the Code of Massachusetts Regulations, 247 CMR 10.03(1), "the Board may impose disciplinary action against an individual or entity licensed or registered by the Board" for violations of the pharmacy laws or regulations, or on one or more other grounds, including:

- "(k) Engaging in conduct that has the capacity or potential to place the public health, safety or welfare at risk;" and
- "(I) Engaging in conduct that has the capacity or potential to deceive or defraud."

247 CMR § 10.03(k) & (l).

Both of these bases for disciplinary action apply in this case. As described above, Ameridose's pre-mixed nicardipine injection product is unsafe, and puts the public health at risk, because its extremely short stability period means that patients who receive the drug will be receiving an expired, outdated, and substandard product. Moreover, because Ameridose represents that its product is safe and stable for much longer than 24 hours after being filled, when in fact the FDA has determined that the product is stable for no more than 24 hours, Ameridose's activities are deceptive.



CONCLUSION

Ameridose's unapproved pre-filled nicardipine I.V. product is unsafe and unlawful, and the Board should take immediate action to prevent further distribution of this product.

Please contact the undersigned if you have any questions or require additional information.

·Respectfully submitted,

fin Cnaban/ve James N. Czaban

Nathan S. Cardon

CC:



1776 K STREET NW
WASHINGTON, DC 20006
PHONE 202.719.7000
FAX 202.719.7049

7925 JONES BRANCH DRIVE McLEAN, VA 22102 PHONE 703.905.2800 FAX 703.905.2820

www.wileyrein.com

Received

JAN 18 2011

BOARD OF PHARMACY

January 14, 2011

James N. Czaban 202.719.7411 jczaban@wileyrein.com

VIA UPS

James D. Coffey, Director Board of Registration in Pharmacy 239 Causeway Street, 2nd Floor, Suite 200 Boston, MA 02114

Contains Confidential Commercial Information and Trade Secrets; Exempt From Public Disclosure Pursuant to Massachusetts Public Records Law, G. L. c. 4, § 7(26)(g)

Re: Pre-Mixed Nicardipine Injection -

Notice of Settlement Between

and Ameridose LLC

Dear Mr. Coffey:

On behalf of and further to our prior correspondence, I am writing to inform you that and Ameridose LLC ("Ameridose") have reached an amicable resolution to the companies' dispute regarding Ameridose's activities involving nicardipine.

Accordingly no longer believes that any governmental investigative or enforcement actions against Ameridose are necessary to protect the public health and safety and hereby withdraws its request that the Board of Registration in Pharmacy take any such actions.

We appreciate your attention to this matter.

Respectfully submitted,

Iames N. Czaban

.cc:

Gregory Conigliaro (Ameridose LLC)